UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	MDL Docket No. 2738
This Document Relates To All Cases	

DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE PLAINTIFFS' EXPERTS' OPINIONS UNRELATED TO GENERAL CAUSATION

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Plaintiffs seek to have four expert witnesses – Drs. Alan Campion, David Kessler, Laura M. Plunkett and April Zambelli-Weiner – offer various opinions that are not related to the fundamental and pertinent question at hand: whether talc is capable of causing ovarian cancer. Specifically:

- Dr. Campion seeks to opine that Raman spectroscopy is a reliable technique for identifying talc particles in human tissues, including ovarian tissues;

- Dr. Zambelli-Weiner seeks to opine that certain talc studies by Drs. Michael Huncharek and Jonathan Muscat were erroneous and industry-driven, and that the United States Food & Drug Administration's ("FDA's") 2014 denial of a Citizen's Petition seeking to require an ovarian cancer warning was improperly influenced by these studies;

- Drs. Kessler and Plunkett both seek to opine about various legal and regulatory matters, such as the requirements of the FDA and whether the J&J defendants complied with them; and

- Dr. Plunkett also seeks to opine on the reasonableness of the J&J defendants' conduct and their purported influence on governmental bodies.

These opinions should be excluded for multiple reasons.

First, they are irrelevant to general causation, which is the subject of this *Daubert* proceeding. Whether Raman spectroscopy (or any other technique for that matter) is capable of identifying talc particles in human tissue does not speak to whether talc use is capable of causing ovarian cancer – and Dr. Campion testified at his deposition that he is not offering any causation opinion in this litigation. Dr. Zambelli-Weiner's criticisms of the 2003 and 2007 Huncharek

studies are similarly irrelevant to the general causation question because none of defendants' experts focus on these studies in reaching their conclusions. Nor does Zambelli-Weiner's speculation about what impact Drs. Huncharek and Muscat had on the FDA's response to the Citizen's Petition have any bearing on what the peer-reviewed scientific literature actually says about whether talc use causes ovarian cancer. Finally, the regulatory opinions offered by Drs. Kessler and Plunkett, as well as Dr. Plunkett's additional opinions regarding the J&J defendants' alleged misconduct in attempting to "influence" regulatory bodies, also do not go to the question of general causation. Indeed, as Dr. Kessler makes clear in his report, the regulatory standards on which the experts' opinions are based are "less stringent" than the standard for "proof of a causal association."[1] In short, these opinions are irrelevant to plaintiffs' central theory of general causation and should therefore be excluded.

Second, Drs. Campion and Zambelli-Weiner's opinions are separately inadmissible because they are unreliable. Dr. Campion's Raman spectroscopy opinion is unreliable because it was commissioned exclusively for litigation purposes. Prior to being approached by plaintiffs' counsel in this litigation, Dr. Campion had no "interest in doing research," which is why he had not authored a

[1] (Expert Report of David A. Kessler, M.D. ("Kessler Rep.") ¶ 68, Nov. 16, 2018 (attached as Ex. C15 to Omnibus Certification of Julie Tersigni, Esq. ("Tersigni Cert.")).)

single paper in nearly a decade. All of that magically changed once plaintiffs' counsel met with Dr. Campion, who proceeded to publish a paper that purported to demonstrate his ability to identify talc particles in human tissue by way of Raman spectroscopy. That paper did not disclose that Dr. Campion and his co-author, Dr. John Godleski, were retained (and paid) to do the work by plaintiffs' lawyers for purposes of talcum powder litigation. While this was Dr. Campion's first venture into the talc litigation, Dr. Godleski has long been an expert for the plaintiffs, having written several reports, testified at multiple trials and been involved (and excluded) in the *Kemp* hearing before Judge Nelson C. Johnson. This backdrop lays bare that Dr. Campion's opinion was generated with an eye towards financial gain rather than a genuine interest in breaking new ground on a scientific subject, calling the reliability of his testimony into serious question.

Dr. Zambelli-Weiner's opinion that the FDA's 2014 denial of the Citizen's Petition was "based on flawed data" is separately inadmissible because it is speculative and unreliable. Dr. Zambelli-Weiner baldly alleges that the FDA gave the Huncharek studies undue weight in its analysis, but ultimately admits that she actually has no idea what the FDA considered in its review of the evidence, or the weight it gave to various studies. And the FDA's letter denying the Citizen's Petition explicitly states that it conducted its own independent review of relevant

literature. Accordingly, Dr. Zambelli-Weiner's opinion is based on nothing but her own *ipse dixit*, and is actually contradicted by the available evidence.

Third, the Court should also independently exclude all of Dr. Kessler's opinions and Dr. Plunkett's non-causation opinions because these experts seek to opine on subjects that are not within the province of expert testimony. For starters, Drs. Kessler and Plunkett's reports are replete with legal opinions, including citations to federal laws and FDA regulations, followed by bottom-line conclusions about whether the J&J defendants complied with those standards. Courts have previously barred these very experts from offering such quintessential legal opinions – including in other talc litigation. *See generally* Tentative Ruling Permitting Dr. Plunkett's Opinions in Part, *Lloyd v. Johnson & Johnson*, No. BC628228 (JCCP No. 4872) (Cal. Super. Ct.) (Plaintiff Eva Echeverria only), *appeal pending* ("Plunkett *Echeverria* Ruling") (attached as Ex. E17 to Tersigni Cert.) (excluding Plunkett's testimony in part in a talc case brought on behalf of multiple plaintiffs); *Newman by & through Newman v. McNeil Consumer Healthcare*, No. 10 C 1541, 2013 WL 9936293, at *5 (N.D. Ill. Mar. 29, 2013) (precluding Plunkett from testifying about "what reporting requirements [d]efendants had under FDA regulations and whether [d]efendants met them"); *In re Prograf Antitrust Litig.*, No. 1:11-md-02242-RWZ, 2014 WL 7641156, at *1-2

(D. Mass. Dec. 23, 2014) ("Dr. Kessler is not—and, indeed, cannot be—a legal expert. It is for the court alone to instruct the jury on what the law is.").

In addition, both Drs. Kessler and Plunkett seek to offer subjective summaries of litigation documents and deposition transcripts in the guise of expert opinions. This Court and others have held that such recitations of record evidence do not qualify as expert evidence because jurors are equipped to review the evidence and interpret it as they see fit. *See, e.g.*, *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 441 (D.N.J. 2009) (Wolfson, J.) (experts may not "simply summarize the facts and the depositions of others") (citation omitted). And courts, including this one, have likewise repeatedly held that opinions (like Dr. Plunkett's) seeking to divine a defendant's state of mind are beyond the scope of permissible expert testimony and should be excluded because jurors are fully capable of determining the parties' knowledge and intent based on evidence presented at trial. *See* Plunkett *Echeverria* Ruling at 6-7 (excluding Plunkett's state-of-mind opinions); *Strum v. DePuy Orthopaedics, Inc.*, No. 2011L009352, 2013 WL 3242715, at *1 (Ill. Cir. Ct. Mar. 8, 2013) (similar); *Bracco*, 627 F. Supp. 2d at 440 ("[E]xperts cannot opine on intent.").

For all of these reasons, discussed further below, the Court should exclude all of the opinions being offered by Drs. Campion, Zambelli-Weiner and Kessler, and the non-causation opinions offered by Dr. Plunkett.[2]

BACKGROUND

A. Alan Campion, Ph.D.

Dr. Campion, a professor of chemistry at the University of Texas, was retained by plaintiffs to opine about a technique that he claims can reliably identify the presence of talc particles in human tissues, including ovarian tissue.[3] Dr. Campion defines Raman spectroscopy as "an inelastic light scattering technique that measures the vibrational frequencies of chemical bonds in molecules and solids," providing, in his opinion, "definitive evidence of their identities and structures."[4]

The gist of Dr. Campion's opinion is that he has purportedly "demonstrated the ability to unambiguously identify talc particles using Raman microscopy in a model system and in real tissue samples, prepared using standard surgical

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[2] Plunkett also seeks to "provide[] opinions on certain aspects of the cause and effect relationship" between exposure to talc and ovarian cancer. (*See* Dep. of Laura Plunkett, Ph.D. ("Plunkett Dep.") 33:25-34:9, Dec. 19, 2018 (attached as Ex. B33 to Tersigni Cert.).) Those causation opinions are separately addressed in defendants' General Causation brief.

[3] (*See* Expert Report of Alan Campion, Ph.D. ("Campion Rep.") at 4, Nov. 16, 2018 (attached as Ex. C5 to Tersigni Cert.).)

[4] (*Id.* at 2.)

pathology laboratory protocols."[5] The supposed basis for that "ability" is a single article he authored with others (including Dr. John Godleski, an expert for plaintiffs in other talc litigation) that purports to identify talc in three separate samples.[6] Dr. Campion does not attempt to connect this supposed "ability" to identify talc with Raman spectroscopy to the question of general causation; indeed, he has disclaimed any opinion on causation in this litigation.[7]

Although Dr. Campion has been working with Raman spectroscopy for the duration of his career, it was not until the MDL plaintiffs' lawyers approached him that he formulated an opinion that the technique can be extended to identify the presence of talc particles in human tissues.[8] According to Dr. Campion's own testimony, he was recommended as a potential expert in this litigation by his wife, Dr. Ellen Blair Smith, who is another expert for plaintiffs in this proceeding[9] and has a four-decade friendship with one of plaintiffs' lawyers.[10] Dr. Campion could not have been clearer about his "novel" foray into the application of Raman

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5 (*Id.* at 6.)

6 (*See* Ex. B. to Campion Rep.)

7 (*See* Dep. of Alan Campion, Ph.D. ("Campion Dep.") 44:21-24, Jan. 9, 2019 (attached as Ex. B1 to Tersigni Cert.); *id.* 45:2-4; *id.* 45:8-11; *id.* 67:11-14.)

8 (*See id.* 13:6-8.)

9 (*Id.* 32:9-12.)

10 (Dep. of Ellen Blair Smith, M.D. 13:10-13, Jan. 9, 2019 (attached as Ex. B11 to Tersigni Cert.).)

spectroscopy to talc, testifying that "[p]rior to this case," he had ***never*** looked at ***any*** mineral through Raman spectroscopy – much less talc.[11]

Upon being contacted by the lawyers from Beasley Allen, Dr. Campion proceeded to publish an article entitled *Identification of Foreign Particles in Human Tissues using Raman Microscopy*.[12] The paper was Dr. Campion's first published article in nine years – a long hiatus that he attributed to a loss of "interest in doing research."[13] The paper was funded exclusively with money from plaintiffs' lawyers in this litigation and cost more than $190,000.[14]

Notably, at least two of Dr. Campion's co-authors – Dr. Godleski and Yuwei Fan – also serve as experts for plaintiffs in talcum powder litigation. Although the paper disclosed that "Alan Campion and John J. Godleski have served as consultants and provided expert testimony in talc and other environmental litigation," it did ***not*** specify which "side [they are] on" in the litigation; nor did it specifically disclose that plaintiffs' lawyers were actually funding the research

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[11] (Campion Dep. 50:8-21; *see also, e.g.*, *id.* 68:7-13; Campion Rep. at 1 (stating that he drew on claimed expertise in "developing ***novel*** experimental methods" to develop his opinion here) (emphasis added).)

[12] (*See* Ex. B to Campion Rep.)

[13] (*See* Campion Dep. 44:3-6.)

[14] (*See id.* 103:20-23 (Q. "What sources of funding were there for this paper other than money from plaintiffs' lawyers?" A. "None."); *id.* 99:23-100:1 (Q. "And I've added it up and it's over $190,000. Does that seem right?" A. "If you've added it up, that's correct.").)

being presented.[15] Thus, as Dr. Campion effectively conceded, anyone reading the paper would not have a fair opportunity to assess any potential bias arising out of his financial arrangement with plaintiffs' counsel.[16]

B. David Kessler, M.D., J.D.

Dr. Kessler – a former commissioner of the FDA and now a mainstay litigation expert for plaintiffs in pharmaceutical litigation[17] – has "***not*** been asked to opine on the scientific evidence concerning an association between the use of talcum powder products and ovarian cancer."[18] Rather, his opinions "focus on the responsibilities of cosmetic manufactures, focusing on the regulatory interface between cosmetic manufacturers and the FDA, as well as industry standards."[19]

Specifically, Dr. Kessler purports to lay out the various regulatory standards for cosmetics, including – for example, that "[e]ach ingredient used in a cosmetic

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15 (*Id.* 165:3-20, 200:4-9.)

16 (*See id.* 168:14-19; *see also id.* 200:4-9 (Q. "Did you disclose to the journal in which you published your publication that your research was funded by plaintiffs' lawyers?" A. "No.").)

17 As Dr. Kessler recently testified in an unrelated trial, of the ***28*** different litigations he has been involved in as an expert, he has testified on behalf of the plaintiff in ***24*** of those proceedings. *See* Trial. Tr. 134:10-21, *Russell v. Janssen Research & Dev. LLP*, No. 150500362 (Phila. Ct. Comm. Pls. Apr. 12, 2018) (attached as Ex. E30 to Tersigni Cert.). Moreover, in every litigation in which he has been asked to opine on the adequacy of a label, he has claimed that the label is ***inadequate***. *Id.* 136:16-137:19. These statistics highlight the one-sided nature of Dr. Kessler's approach to product-liability litigation.

18 (Kessler Rep. ¶ 12.)

19 (*Id.*)

product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing";[20] that "[a]ny such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded";[21] that a cosmetic label "shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product";[22] and that a cosmetic is adulterated if it contains "any poisonous or deleterious substance which may render it injurious to users."[23]

It is Dr. Kessler's opinion that "consistent with [these] FDA regulations and statutes, a cosmetic manufacturer . . . must assure the safety of [its] ingredients."[24] Dr. Kessler also quotes at length from various internal company documents that supposedly support the notion that "cosmetic manufacturers have responsibility to substantiate the safety of their product."[25] According to Dr. Kessler, "in light of a) the FDA's 2014 petition response acknowledging that there remains some evidence to suspect or question the safety of talcum powder products, b) the medical literature since 2014 that continues to raise safety questions; and c) IARC's classification, defendants failed to substantiate the safety of their talcum

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20 (*Id.* ¶ 14 (alteration in original) (quoting 21 C.F.R. § 740.10).)

21 (*Id.* ¶ 15 (alteration in original) (quoting 21 C.F.R. § 740.10).)

22 (*Id.* ¶ 17 (quoting 21 C.F.R. § 740.10).)

23 (*Id.* ¶ 19 (quoting 21 U.S.C. § 361).)

24 (*Id.* ¶ 40.)

25 (*Id.* § C (emphasis omitted); *id.* ¶¶ 42-50.)

powder products."[26] Dr. Kessler also claims that defendants' talcum powder products should have contained a warning that their safety had not been determined.[27]

Despite attempting to enumerate various regulatory standards governing cosmetic products, Dr. Kessler nonetheless seeks to opine that "of all the products that fall under FDA's jurisdiction, cosmetics are among the least regulated. This is reflected in the fact that there is no premarket approval of cosmetic products."[28] He also claims that "only very limited resources have ever been committed to cosmetic product review, monitoring, or safety."[29]

C. Laura Plunkett, Ph.D.

Dr. Plunkett is a litigation pharmacologist who also purports to be a toxicologist.[30] In a section of her report purportedly addressing "[t]he [r]egulatory [p]rocess in the United States" for "[t]alcum [p]owder [p]roducts,"[31] Dr. Plunkett selectively quotes and interprets the federal Food, Drug & Cosmetic Act ("FDCA") and its implementing regulations, which she recognizes are designed "to

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26 (*Id.* ¶ 64.)

27 (*Id.* ¶ 65.)

28 (*Id.* ¶ 20.)

29 (*Id.* ¶ 21.)

30 (Expert Report of Laura M. Plunkett, Ph.D., D.A.B.T. ("Plunkett Rep.") ¶ 1, Nov. 16, 2018 (attached as Ex. C28 to Tersigni Cert.).)

31 (*Id.* § III.)

ensure that cosmetics are not '*adulterated*' and '*misbranded.*'"[32] She also opines on the enforcement methods available to the FDA in the area of cosmetics, noting what she characterizes as the general "constraints on FDA's authority" and the FDA's "general lack of regulatory oversight" related to cosmetics.[33] According to Plunkett, "*FDA's authority over cosmetics is less comprehensive than its authority over other FDA-regulated products with regard to GMP; premarket notification; clearance, or approval; testing; and mandatory risk labeling.*"[34]

These opinions serve as the basis for Dr. Plunkett's conclusion that talc-based body powders should carry an ovarian cancer warning.[35] Notably, just like Dr. Kessler, Dr. Plunkett recognizes that the standard for including a warning on cosmetic products is "based on a standard of a ***possibility*** of health hazard, not on having evidence of a ***causal*** association between a health effect and the cosmetic product or ingredient."[36]

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32 (*Id.* ¶¶ 18-19 (characterizing the FDCA and the Fair Packaging and Labeling Act and some requirements of those laws).)

33 (*Id.* ¶¶ 24-27.)

34 (*Id.* ¶ 16 (citation omitted).)

35 (*Id.* ¶¶ 27, 102; *see also id.* ¶ 105 (relying on 21 C.F.R. § 740.1(a) in opining that "a warning about serious tissue toxicity and the increased risk of ovarian cancer with use of talcum powder products should have been included on the product labeling").)

36 (*Id.* ¶ 22 (emphases added).)

Plunkett also devotes a significant portion of her report to the supposed "[r]ole of [i]ndustry in [t]alcum [p]owder [p]roduct [s]afety [a]ssessments."[37] This section of her report consists of a narrative description of a cherry-picked set of defendants' internal documents that she contends support the conclusion that "defendants worked both individually and collaboratively to present a uniform position to regulators, the scientific and medical community, and consumers, that talcum powder product use did not present a risk of ovarian cancer in humans."[38] Rather than offering expert analysis on this topic, Dr. Plunkett seeks merely to testify as to the contents of the documents that she cites and describes.[39]

D. April Zambelli-Weiner, Ph.D.

Dr. Zambelli-Weiner admittedly does not plan to testify about the core issue at this stage of the litigation: whether the "use of Johnson's Baby Powder or Shower to Shower causes ovarian cancer."[40] Rather, she opines that two studies by

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37 (*Id.* § VII; *id.* ¶¶ 76-100.)

38 (*Id.* ¶ 76; *see also id.* ¶ 78 ("[I]n the 1970s, documents show that Johnson & Johnson made efforts to influence the science around the issue of asbestos in talc and the link of talc with ovarian cancer . . . ."); *id.* ¶ 79 (attempting to describe "the role of the [Cosmetic Ingredient Review panel] in cosmetic safety assessments"); *id.* ¶ 80 (similar); *id.* ¶ 83 ("Together with Johnson & Johnson and Imerys, PCPC coordinated and presented a position to regulators and the medical community that talc was safe. This position was presented regardless of significant evidence to the contrary.").)

39 (*See id.* ¶¶ 76-100.)

40 (Dep. of April Zambelli-Weiner, Ph.D. Vol. I ("Zambelli-Weiner Dep.") 46:18-22, Jan. 11, 2019 (attached as Ex. B3 to Tersigni Cert.).)

Dr. Huncharek – a 2003 meta-analysis on perineal talc use (co-authored by Dr. Huncharek and others but not Dr. Muscat) and a 2007 meta-analysis on talc use on diaphragms (co-authored by Dr. Huncharek, Dr. Muscat and others) (together the "2003 and 2007 Huncharek studies")[41] – "contain substantial errors."[42] The alleged errors include "misstatements of underlying data, improper calculations, and [a failure to] utilize generally accepted methodologies and best practices in epidemiology[,] . . . rendering the findings flawed and unreliable."[43] Dr. Zambelli-Weiner argues that the "[t]alc industry" (i.e., defendants) "heavily relied on" the 2003 and 2007 Huncharek studies in a report submitted to the FDA in 2009 (the "2009 report"), in response to the FDA's request for comments on a Citizen's Petition seeking to require an ovarian cancer warning label on talc products.[44]

The FDA denied the Citizen's Petition in 2014 because it "did not find that the data submitted presented conclusive evidence of a causal association between

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41 Huncharek et al., *Perineal Application of Cosmetic Talc and Risk of Invasive Epithelial Ovarian Cancer: A Meta-Analysis of 11,933 Subjects from Sixteen Observational Studies*, 23 Anticancer Res. 1955 (2003) (attached as Ex. A67 to Tersigni Cert.); Huncharek et al., *Use of Cosmetic Talc on Contraceptive Diaphragms and Risk of Ovarian Cancer: A Meta-Analysis of Nine Observational Studies*, 16 Eur J Cancer Prev. 422 (2007) (attached as Ex. A68 to Tersigni Cert.).

42 (Expert Report of April Zambelli-Weiner, Ph.D., M.P.H. ("Zambelli-Weiner Rep.") at 6-7, Nov. 16, 2018 (attached as Ex. C8 to Tersigni Cert.).)

43 (*Id.*)

44 (*Id.* at 7-8 ("these articles and the analyses in them were a primary focus of the arguments advanced by the talc industry in opposition to a mandatory cancer warning").)

talc use in the perineal area and ovarian cancer."[45] Dr. Zambelli-Weiner believes that this determination was invalid because it was based on "flawed data" – i.e., the 2009 report, which discussed the 2003 and 2007 Huncharek studies.[46] Specifically, she argues that the 2003 and 2007 Huncharek studies "assumed added importance from a regulatory and policy perspective due to the fact that the authors attributed added weight to [them] . . . in advocating them to the FDA in 2009."[47] She ultimately opines that "[a]ny scientific, regulatory or policy deliberations or decisions, including but not limited to those undertaken and issued by the FDA, that relied upon the data and analyses put forward by Drs. Huncharek and Muscat, in whole or in part, are based on flawed data, calculations and conclusions."[48]

ARGUMENT

The opinions being offered by Drs. Campion, Kessler, Plunkett and Zambelli-Weiner should be excluded for multiple reasons: (1) they are irrelevant to the fundamental question of general causation presently being considered by this Court; (2) Dr. Campion's opinion is unreliable in light of the fact that it is based

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45 Letter from Steven M. Musser, Ph.D., Deputy Dir. for Sci. Operations, Ctr. for Food Safety & Applied Nutrition, to Samuel S. Epstein, M.D., Cancer Prev. Coalition, Univ. of Ill. – Chi. School of Pub. Health, at 1 (Apr. 1, 2014) ("FDA Denial Letter") (attached as Ex. A89 to Tersigni Cert.).

46 (Zambelli-Weiner Rep. at 7.)

47 (*Id.* at 9.)

48 (*Id.* at 7.)

entirely on research funded by plaintiffs' counsel in this litigation and was expressly developed for litigation; (3) Dr. Zambelli-Weiner's opinion regarding the FDA's review of evidence is unreliable speculation; and (4) Dr. Kessler's opinions and Dr. Plunkett's non-causation-related opinions would not qualify as proper expert testimony even if relevant.

I. DRS. CAMPION, KESSLER AND ZAMBELLI-WEINER'S OPINIONS, AND MANY OF PLUNKETT'S OPINIONS, LACK THE REQUISITE FIT WITH PLAINTIFFS' THEORY OF GENERAL CAUSATION.

Under Rule 702, the opinions of an expert witness are only admissible if they "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). As the Supreme Court has explained, this "'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591-92 (1993); *see also Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 527 (W.D. Pa. 2003) ("The 'fit' requirement stems from the instruction of Federal Rule of Evidence 702 that proffered expert testimony must 'assist . . . the trier of fact.'"). "The consideration has been aptly described . . . as one of 'fit,'" which "goes primarily to relevance." *Daubert*, 509 U.S. at 591 (citation omitted).

Consistent with this principle, where an expert's opinion does "not fit the central question at issue in the case," her opinion is properly excluded. *Buzzerd v. Flagship Carwash of Port St. Lucie, Inc.*, 397 F. App'x 797, 800 (3d Cir. 2010)

(affirming exclusion of expert's opinion that there were pathways through which carbon monoxide ***might*** have reached the passenger cabin because "the central issue that the jury would have been called upon to decide in the case was . . . 'whether it is *probable* that vehicle emissions *would* enter the passenger compartment under operating conditions'"; thus, expert's "testimony did not fit the central question at issue in the case") (citation omitted); *see also, e.g.*, *In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 668 (D.N.J. 2008) (excluding opinion from expert that "fails to fit the challenged general causation at issue in the case"); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1407 (D. Or. 1996) ("[T]o the extent that plaintiffs intended to use Dr. Swan's testimony to support their argument that silicone breast implants can cause ACTD, I have already ruled that no testimony regarding ACTD will be permitted. Therefore, Dr. Swan's testimony is now a stepping stone that leads nowhere; it no longer 'fits' plaintiffs' case."); *Soldo*, 244 F. Supp. 2d at 564 (excluding expert's causation opinion for lack of fit where the plaintiff's theory was that a prescription drug caused intracranial hemorrhagic stroke and the expert's causation theory was focused on ischemic stroke, a different kind of stroke); *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d 430, 542 (S.D.N.Y. 2018) (concluding that, where the plaintiffs "never alleged an entitlement to recover for damages incurred as a

result of macroeconomic events," expert opinions that purported to measure such damages did not fit the case and would not be considered).

All of Drs. Campion, Kessler and Zambelli-Weiner's opinions, and many of Dr. Plunkett's opinions, are irrelevant to plaintiffs' general causation theory, and therefore inadmissible, for the following reasons.

Dr. Campion. As explained above, Dr. Campion seeks to opine that "Raman spectroscopy is a reliable and unambiguous method for identifying talc and asbestos bodies in human tissue as well as in inorganic materials."[49] But the ability to identify such minerals says ***nothing*** about whether talc (or any asbestos in talc) is capable of causing ovarian cancer, which is the question presently at issue. Dr. Campion effectively conceded as much at his deposition, testifying that he did not know whether the talc particles in the ovarian sample examined in the paper "got there through" perineal talc use as opposed to some other source.[50] Similarly, Dr. Campion was clear that he had "***absolutely no idea***" of the baseline amount of talc in a person's cells without the use of talc – much less whether the talc in the ovarian cells that were used in the paper was above or below that baseline.[51]

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49 (Campion Rep. at 6.)

50 (*See* Campion Dep. 80:13-19.)

51 (*Id.* 81:2-10 (emphasis added).)

Moreover, when asked whether he would be offering an opinion on disease causation in this litigation, Dr. Campion definitively answered no and added that he did not "know how [he] could."[52] Nor was Dr. Campion aware of any plans to use the techniques set forth in his paper and report on actual slides from actual plaintiffs in the talc MDL proceeding.[53] In short, Dr. Campion's opinion has nothing to do with the fundamental question of general causation and should therefore be excluded.

Dr. Zambelli-Weiner. Dr. Zambelli-Weiner's opinions are also irrelevant to the issue of general causation. Dr. Zambelli-Weiner opines that the FDA considered "flawed data" – specifically the 2009 report, which discussed the 2003 and 2007 Huncharek studies – in denying the Citizen's Petition in 2014.[54] But even assuming, arguendo, that Dr. Zambelli-Weiner's criticisms of these studies were correct, the idea that the FDA might have relied in part on erroneous data in 2014 says nothing about whether the comprehensive talc literature itself supports an inference that talc use causes cancer.

Moreover, Dr. Zambelli-Weiner's criticisms of the 2003 and 2007 Huncharek studies, although detailed, are likewise ultimately irrelevant. For one thing, Dr. Zambelli-Weiner's criticisms of the 2003 and 2007 Huncharek studies

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52 (*Id.* 44:24-45:1; *see also id.* 45:2-11 (similar).)

53 (*See id.* 117:3-17.)

54 (Zambelli-Weiner Rep. at 7.)

are irrelevant because her own reanalysis of the data in those studies failed to generate materially different results. Most notably, Dr. Zambelli-Weiner attacks the 2003 study's conclusion that its data showed no dose response, but her reanalysis of the data likewise showed no dose response.[55] Similarly, Dr. Zambelli-Weiner attacks the 2007 study's conclusion that its data did not show an increased risk of ovarian cancer from use of talc on diaphragms, but her reanalysis of those data resulted in an ***even lower*** risk estimate than the one reported in the study.[56] Dr. Zambelli-Weiner's failure to invalidate these findings is unsurprising, since as set forth in defendants' General Causation brief, the broader talc literature does not show a dose response or an association between talc use on diaphragms

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[55] Table 2 in Dr. Zambelli-Weiner's report sets forth her results from reanalyzing the data from the 2003 Huncharek study using multiple data aggregation methodologies. (Zambelli-Weiner Rep. at 20 tbl. 1.) The 2003 study had reported finding no dose response based on a 1.83 odds ratio for the lowest exposure category versus a 1.21 odds ratio for the highest category. (*Id.*) Dr. Zambelli-Weiner claims that she was unable to regenerate the 1.83 figure (*id.* at 19), but nevertheless, the data in her table continue to show (in nearly all instances) a lower odds ratio for the higher-exposure group (*id.* at 20; *see also* Expert Report of Karla Ballman, Ph.D. ("Ballman Rep.") at 35, Feb. 25, 2019 (attached as Ex. C25 to Tersigni Cert.) (explaining that Dr. Zambelli-Weiner's reanalysis produced "different estimates of the risk ratios but still did not provide evidence of a dose-response relationship")).

[56] (*See* Zambelli-Weiner Rep. at 29 tbl. 4 (table setting forth results of reanalysis of data in 2007 Huncharek study, reporting non-significant odds ratios of 0.88 and 0.74 based on multiple aggregation techniques; compare with non-significant 1.03 odds ratio reported in 2007 study).)

and ovarian cancer, meaning that excluding the 2003 and 2007 Huncharek studies from review, as Dr. Zambelli-Weiner recommends, would change nothing.

This is all the more so in light of the fact that defendants' experts address the 2003 and 2007 Huncharek studies, at most, in passing and instead rely on the overall body of literature.[57] Moreover, several of defendants' experts acknowledge Dr. Zambelli-Weiner's criticisms of the 2003 and 2007 Huncharek studies but point out that these issues did not affect the studies' ultimate conclusions, as explained above.[58] And none of defendants' experts relies on the 2009 report.[59]

For all of these reasons, Dr. Zambelli-Weiner's opinions are irrelevant to the question of general causation.

Drs. Kessler and Plunkett. The proposed testimony from Drs. Kessler and Plunkett is similarly irrelevant to this general causation proceeding. As Dr.

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[57] Several of defendants' experts cite a different meta-analysis by Drs. Huncharek and Muscat that Dr. Zambelli-Weiner does not criticize. (*See, e.g.*, Expert Report of Gregory Diette, M.D., M.H.S. ("Diette Rep."), Feb. 25, 2019 (attached as Ex. B26 to Tersigni Cert.) (citing Muscat & Huncharek, *Perineal Talc Use and Ovarian Cancer: A Critical Review*, 17(2) Eur J Cancer Prev. 139, 144-45 (2008)).)

[58] (Ballman Rep. at 35; Diette Rep. at 14 n.51; Expert Report of Christian Merlo, M.D., M.P.H. at 28 n.62, Feb. 25, 2019 (attached as Ex. C13 to Tersigni Cert.).)

[59] Dr. Tuttle mentions the 2011 publication of the 2009 report in passing, noting both that it was published and that it "conclude[d] that the available epidemiological studies do not support a causal association" between perineal talc use and ovarian cancer, but the publication does not play any significant role in her opinions. (Expert Report of Kelly Scribner Tuttle, Ph.D., C.I.H. at 26, Feb. 25, 2019 (attached as Ex. C26 to Tersigni Cert.).)

Kessler's report explains, his "opinions . . . focus on the responsibilities of cosmetic manufacturers" – specifically, "the regulatory interface between cosmetic manufacturers and the FDA, as well as industry standards."[60] In other words, while Dr. Kessler attempts to "address the duties of cosmetic manufacturers to warn in the face of a potential health hazard," he "ha[s] ***not*** been asked to opine on the scientific evidence concerning an association between the use of talcum powder products and ovarian cancer,"[61] which is the pertinent causal theory at issue in this case. And although Dr. Plunkett offers a range of causation-related opinions – which should be excluded for a host of reasons, as set forth in defendants' General Causation brief – she also offers a series of highly irrelevant opinions regarding regulations applicable to cosmetic manufacturers and her bottom-line conclusion that "a warning about serious tissue toxicity and the increased risk of ovarian cancer with use of talcum powder products should have been included on the product labeling."[62]

Notably, Dr. Kessler expressly states that the "regulatory standard" for warning about a potential health hazard "is ***less*** stringent than proof of a ***causal*** association."[63] Dr. Plunkett is similarly emphatic in distinguishing the standard

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60 (Kessler Rep. ¶ 12.)

61 (*Id.* (emphasis added).)

62 (Plunkett Rep. ¶ 105 (relying on 21 C.F.R. § 740.1(a)).)

63 (Kessler Rep. ¶ 68 (emphases added).)

governing warnings from that applicable to causation, stating that "[c]ause and effect do ***not*** have to be proven for such a warning to be put into place."[64]

These fundamental distinctions between regulatory standards and the sort of proof required for establishing causation make perfect sense. Regulatory agencies employ a risk-utility analysis that is distinct from the scientific standard demanded by a court of law. *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002). By contrast, courts are "required by the *Daubert* trilogy to engage in objective review of evidence to determine whether it has sufficient scientific basis to be considered reliable." *Id.* ("The district court did not abuse its discretion in concluding that the FDA actions do not, in this case, provide scientific proof of causation."); *see also, e.g.*, *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) (per curiam) (government agencies employ a preventative perspective that is aimed at reducing public exposure, which requires a lesser showing of harm than the preponderance of the evidence standard); *Soldo*, 244 F. Supp. 2d at 513 ("FDA decision-making is based on a different standard than tort law-based scientific proof of causation."); *In re Zicam Cold Remedy Mktg., Sales Practices, & Prods. Liab. Litig.*, No. 09-md-2096-PHX-FJM, 2011 WL 798898, at *11 (D. Ariz. Feb. 24, 2011) ("[A]gency actions are not the result of a *Daubert*

[64] (Plunkett Rep. ¶ 118; *see also id.* ¶ 22 (standard for including a warning on cosmetic products is "based on a standard of a ***possibility*** of health hazard, not on having evidence of a ***causal*** association between a health effect and the cosmetic product or ingredient.") (emphases added).)

level of scrutiny, but rather reflect the agency's purpose to protect the 'public-at-large from risk of harm based on a risk-utility analysis of the drug.' This risk-utility approach employs a lower standard than a scientific causation approach requires.") (citation omitted). In short, regulatory standards are no substitute for the scientific causation standard required by a court of law.

Drs. Kessler and Plunkett's opinions regarding the FDA's supposedly "limited oversight of cosmetics products" and their claim that such regulation "is less stringent than the regulation of drugs, medical devices, and food additives,"[65] are even less relevant to the question of causation. After all, even assuming that these opinions are valid, they say nothing about whether talcum powder products are capable of causing ovarian cancer.

The same is true with respect to Dr. Plunkett's opinions regarding the "[r]ole of [i]ndustry in [t]alcum [p]owder [p]roduct [s]afety [a]ssessments."[66] These opinions all boil down to Dr. Plunkett's subjective assertion that defendants sought

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65 (Kessler Rep. ¶¶ 22, 34; *see also* Plunkett Rep. ¶¶ 24-27 (opining about "constraints on FDA's authority" and "general lack of regulatory oversight" over cosmetics).)

66 (Plunkett Rep. § VII; *id.* ¶¶ 76-100.)

to "influence" the regulation of talc[67] – which does not remotely speak to the question whether talc is capable of causing ovarian cancer.[68]

In sum, these opinions by Drs. Campion, Kessler, Plunkett and Zambelli-Weiner all "fail[] to fit the challenged general causation at issue in the case," *In re Human Tissue*, 582 F. Supp. 2d at 668 – i.e., ***whether perineal talc use can cause ovarian cancer***. Instead, they are essentially "a stepping stone that leads nowhere" and therefore should be excluded. *Hall*, 947 F. Supp. at 1407. For this reason alone, the Court should exclude Dr. Campion's opinion, all of Dr. Zambelli-Weiner and Dr. Kessler's opinions, and all of Dr. Plunkett's opinions regarding

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67 (*See id.* ¶ 93.)

68 If evidence of purported efforts to influence regulators were relevant, the same would be true of the far more recent (indeed, ongoing) and direct efforts by plaintiffs' experts to influence the regulatory process in Canada. In particular, after she was deposed, Dr. McTiernan sent a submission to Health Canada in February 2019 (*see* Email Submission of Anne McTiernan, M.D., Ph.D. to Health Canada, Feb. 5, 2019 (attached as Ex. F1 to Tersigni Cert.)), and subsequent correspondence indicates the possibility of further "phone calls, email exchanges, or even short term contracts" (*see* Email Exchange between Anne McTiernan, M.D., Ph.D. and Scott Hancock, Health Canada, Feb. 21, 2019 (attached as Ex. F3 to Tersigni Cert.)). Dr. Siemiatycki also submitted his opinions to Health Canada after he was deposed and carried on an extended correspondence that included providing the regulator with his MDL report. (*See* Letter from Jack Siemiatycki, M.Sc., Ph.D. to Health Canada, Feb. 6, 2019 (attached as Ex. F2 to Tersigni Cert.); Email Exchange between Jack Siemiatycki, M.Sc., Ph.D. and Scott Hancock, Health Canada, Mar. 2019 (attached as Ex. F5 to Tersigni Cert.).) And Dr. Saed recently emailed Health Canada regarding his made-for-litigation manuscript without so much as mentioning his role as a paid expert. (*See* Dep. of Ghassan Saed, Ph.D. Vol. 2 533:16-535:23, 564:2-6, Feb. 14, 2019 (attached as Ex. B19 to Tersigni Cert.); Email Exchange between Ghassan Saed, Ph.D. and Scott Hancock, Health Canada (Feb.-Mar. 2019) (attached as Ex. F4 to Tersigni Cert.).)

regulatory matters and defendants' supposed "influence" with regard to the regulation of talc.

II. DR. CAMPION'S ENTIRE OPINION AND DR. ZAMBELLI-WEINER'S OPINION ABOUT THE BASIS FOR THE FDA'S PETITION DENIAL ARE UNRELIABLE AND INADMISSIBLE.

Even if Dr. Campion's opinion regarding Raman spectroscopy and Dr. Zambelli-Weiner's opinions regarding the FDA's petition denial had any relevance to the question of general causation, they would still be inadmissible because they are unreliable.

A. Dr. Campion's Opinion Is Unreliable Because It Is Based Entirely On Research Bankrolled By Plaintiffs' Counsel.

Dr. Campion's opinion should also be excluded because his research was bought and paid for by plaintiffs' counsel. "[C]lose judicial analysis of expert testimony is necessary 'because expert witnesses are not necessarily always unbiased scientists.'" *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 252 (6th Cir. 2001) (citation omitted). Thus, an "expert's motivation for his/her study and research is important" in gauging the overall reliability of an expert's ultimate opinions. *Soldo*, 244 F. Supp. 2d at 527-28 (citation omitted). When that motivation is primarily financial in nature, there is a significant danger that pecuniary interests rather than genuine science is driving that research. *See Braun v. Lorillard Inc.*, 84 F.3d 230, 235-36 (7th Cir. 1996) (referring to "abuse" of hiring scientists "to testify for a fee to propositions that they have not arrived at

through the methods that they use when they are doing their regular professional work"); *see also Nelson*, 243 F.3d at 252 ("[T]he magistrate did not abuse his discretion by . . . concluding that 'the fact that the study was . . . funded by plaintiffs' counsel does not militate in Dr. Kilburn's favor.'") (citation omitted).

Such is the case here. Prior to being contacted by plaintiffs' lawyers in this litigation (apparently at the urging of Dr. Campion's wife, another expert for plaintiffs' counsel in this litigation), Dr. Campion had little "interest in doing research."[69] Such a sentiment explains why Dr. Campion had not authored a single paper in the nine years before he was asked to serve as an expert in this litigation.[70] Nonetheless, armed with funding ***exclusively*** from plaintiffs' lawyers in this case, Dr. Campion proceeded to write a paper with another expert for plaintiffs in the talc litigation, Dr. Godleski, and a few others, that purportedly "demonstrated [their] ability to obtain high quality Raman spectra of talc particles embedded in real tissue samples."[71] Dr. Campion so proceeded even though he had never looked at talc through Raman spectroscopy prior to his lawyer-funded experiment.[72] These circumstances strongly suggest that the research underlying Dr. Campion's opinion in this litigation was fueled by a pecuniary interest, as

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69 (Campion Dep. 44:3-6.)

70 (*Id.*)

71 (Campion Rep. at 4; Campion Dep. 103:2-23.)

72 (*See* Campion Dep. 68:7-13.)

opposed to a genuine quest for the scientific truth, fatally undermining the reliability of his ultimate opinion.

Such a conclusion is all the more warranted given that the paper underlying Dr. Campion's expert report does not adequately disclose that it was funded by the plaintiffs' lawyers in this proceeding. *See In re Garlock Sealing Techs., LLC*, 504 B.R. 71, 79 (Bankr. W.D.N.C. 2014) (finding expert's studies unreliable in part because "[t]he materials used in the studies were provided with funding by plaintiffs' attorneys, but that fact was not disclosed"). To be sure, the paper states under a heading titled "Notes" that "Alan Campion and John. J. Godleski have served as consultants and provided expert testimony in talc and other environmental litigation."[73] However, as Dr. Campion fully acknowledged at his deposition, that generic disclosure did not even remotely indicate which "side [they were] on"; nor did it purport to disclose that the research presented was being funded by plaintiffs' lawyers in litigation.[74] As Dr. Campion further conceded, the lack of such basic disclosures effectively forecloses "the reader" from "hav[ing] an opportunity to evaluate th[e] potential bias that [he] w[as] being paid by a law firm at the time [he] w[as] writing this paper and for [his] work on that paper."[75]

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73 (Ex. B to Campion Rep. at 8.)

74 (Campion Dep. 165:4-20; *id.* 200:4-9.)

75 (Campion Dep. 165:4-20; *id.* 168:14-19.)

In sum, not only was Dr. Campion's brand-new opinion with regard to the application of Raman spectroscopy to talc effectively bought by plaintiffs' counsel, but the authors hid that important fact from the public domain and the individuals who peer-reviewed the paper on which that opinion is based. Under these circumstances, Dr. Campion's opinion cannot be deemed sufficiently credible to pass muster under *Daubert.* For this reason, too, the Court should exclude Dr. Campion's opinion.

B. Dr. Zambelli-Weiner's Opinions Are Rank Speculation.

Dr. Zambelli-Weiner's opinion that the FDA's petition denial was unduly influenced by the 2009 report and 2003 and 2007 Huncharek studies is unreliable because it is pure speculation. *See, e.g.*, *Rheinfrank v. Abbott Labs., Inc.*, 680 F. App'x 369, 388 (6th Cir. 2017) (refusing to countenance a "series of speculations as to what the FDA *could* have done with different evidence that Abbott *might* have collected *if* it had run its own studies").[76] Dr. Zambelli-Weiner has no

[76] *See also In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 550 n.62 (S.D.N.Y. 2004) ("To the extent that Dr. Tolman's testimony relates to disclosures to the FDA or speculation as to what FDA might have done in hypothetical circumstances, it is excluded . . . ."); *Webster v. Pacesetter, Inc.*, 259 F. Supp. 2d 27, 37 (D.D.C. 2003) (plaintiffs cannot "speculat[e] that *if* the FDA had known of the delayed perforation and tamponade incidents during the clinical trials and *if* defendant had investigated all the adverse incidents, the FDA would have either recalled the lead or placed it on alert, and therefore, Dr. Lewis would not have implanted it in plaintiff's heart" because such an "approach would be nothing more than an invitation for the jury to speculate about what both the FDA and Dr. Lewis might do if the facts were different").

particular knowledge of how the FDA's review process actually unfolded and does not purport to have reviewed testimony or documents (other than the FDA Denial Letter itself) setting forth the materials considered in denying the petition.[77] Indeed, she concedes that she does not "know the inner workings of who reviewed what as part of [the petition denial]" and "can't say what exactly [the FDA] reviewed and what weight they gave to any particular piece of evidence" when considering materials for the Citizen's Petition.[78] And since she does not know how, if at all, the FDA weighed the 2009 report and 2003 and 2007 Huncharek studies, she admits that she cannot conclude that the FDA's conclusion would have been any different without them.[79]

Instead, her central contention that the FDA placed undue weight on the 2009 report (and by extension the 2003 and 2007 Huncharek studies) appears to be

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[77] Even if she had conducted such a review, Dr. Zambelli-Weiner, who is an epidemiologist, not a regulatory expert, would not be qualified to opine about the FDA's process, and the jury would be equally capable of reviewing such materials, if they existed. (*See* Zambelli-Weiner Rep. at 5-6; Zambelli-Weiner Dep. 109:9-12 ("Q: You're not an FDA expert, correct? A: I am not – correct, I am not a regulatory expert.") (objection omitted).)

[78] (Zambelli-Weiner Dep. 124:1-12, 170:7-8, 179:5-7; *id.* 124:1-12, 169:24-170:25 (admitting that she did not know the process at the FDA for reviewing or responding to the Citizen's Petition, who at the FDA relied on the 2003 and 2007 Huncharek studies or on which specific parts of the studies the FDA might have relied); *id.* 171:4-19, 178:25-179:8 (testifying that she did not know how much weight the FDA placed on the 2003 and 2007 Huncharek studies, the extent or nature of the FDA's reliance on them or what else the FDA relied on).)

[79] (Zambelli-Weiner Dep. 180:10-19 (admitting that she could not "say that any particular outcome would have been different").)

based mostly on the fact that the 2009 report "was the only comment received by the FDA in response to the Citizen's Petition."[80] This is a massive inferential leap that is flatly contradicted by the FDA's letter, which stated, among other things, that the FDA conducted its own "expanded literature search dating from the filing of the petition in 2008 through January 2014."[81] *See Ortiz v. Yale Materials Handling Corp.*, No. CIV 03-3657FLW, 2005 WL 2044923, at *9-10 (D.N.J. Aug. 24, 2005) (Wolfson, J.) (excluding expert whose opinions were *ipse dixit* and who relied on a study that "actually support[ed] [the] [d]efendant's position").[82] Finally, to the extent Dr. Zambelli-Weiner's argument is that "[a]ny" reliance on the 2009 report and 2003 and 2007 Huncharek studies invalidates all of the FDA's determinations, this is inadmissible *ipse dixit* as well, since she provides no methodology for concluding that the FDA's entire analysis is void based on next to

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80 (Zambelli-Weiner Rep. at 8, 36.)

81 FDA Denial Letter at 6.

82 Although Dr. Zambelli-Weiner additionally argued at her deposition that heavy reliance on the 2009 Huncharek and Muscat report is demonstrated by the fact that "a lot of the language and arguments and positions that were proffered in [it] are echoed in FDA's denial letter" (Zambelli-Weiner Dep. 170:15-25), these observations also amount to mere conjecture (and non-expert conjecture at that) in light of her repeated concessions that she has essentially no knowledge of the FDA's process other than what is described in the FDA Denial Letter.

no knowledge about how it was conducted. For this reason, too, her opinions should be excluded under *Daubert*.[83]

III. ALL OF DR. KESSLER'S OPINIONS AND MANY OF DR. PLUNKETT'S NON-CAUSATION OPINIONS SHOULD BE EXCLUDED BECAUSE THEY ARE NOT THE SUBJECT OF PROPER EXPERT TESTIMONY.

A. Drs. Kessler And Dr. Plunkett's Regulatory Opinions Amount To Improper Legal Conclusions That Are Not The Proper Subject Of Expert Testimony.

Separate and apart from their irrelevance, Drs. Kessler and Plunkett's opinions are also inadmissible because they both offer improper legal opinions.

"Although Federal Rule of Evidence 704 permits an expert witness to give expert testimony that 'embraces an ultimate issue to be decided by the trier of fact,' an expert witness is prohibited from rendering a legal opinion." *Flickinger v. Toys "R" Us-Del., Inc.*, 492 F. App'x 217, 224 (3d Cir. 2012) (citations omitted). "This prohibition on experts testifying as to their own legal conclusions is 'so well established that it is often deemed a basic premise or assumption of evidence of law—a kind of axiomatic principle'" that has been adopted by "every circuit." *Holman Enters. v. Fid. & Guar. Ins. Co.*, 563 F. Supp. 2d 467, 472 (D.N.J. 2008) (citations omitted). As the Third Circuit has explained, such opinions "interfere

[83] Dr. Zambelli-Weiner's opinions are notably at odds with those of plaintiffs' other experts, who pick and choose portions of the FDA Denial Letter (in particular, its statement about the ability of talc to migrate to the ovaries) that they claim support their opinions.

with the district court's 'pivotal role in explaining the law to the jury.'" *Patrick v. Moorman*, 536 F. App'x 255, 258 (3d Cir. 2013) (quoting *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006)). Moreover, "[e]xpert testimony is an improper mechanism for offering legal arguments to the [c]ourt . . . [because it] would be unfair to [one party] for the [c]ourt to award [the opposing party's] legal arguments the elevated stamp of expert." *Fisher v. Halliburton*, No. H-05-1731 et al., 2009 WL 5216949, at *2 (S.D. Tex. Dec. 21, 2009) (citation omitted).

Both Drs. Plunkett and Kessler have been previously barred from offering legal opinions at trial based on these same principles. Most recently, a court presiding over talcum powder cases in California barred Dr. Plunkett from opining that talc-based powders should have been labeled to warn of certain risks, recognizing that this was an impermissible legal opinion. Plunkett *Echeverria* Ruling at 6 ("Dr. Plunkett is also precluded from opining that talc based powder should have been labelled to warn of the risks" because such an opinion is an improper "legal opinion."). Likewise, the court in *Newman* precluded Dr. Plunkett from testifying about "what reporting requirements [d]efendants had under FDA regulations and whether [d]efendants met them," noting that much of her testimony "consists of quoted portions of the [FDA] regulations themselves or descriptions of what the regulations require," which was "unnecessary," and risked jurors

"mistakenly conclud[ing] that her opinion or conclusion is the law." 2013 WL 9936293, at *5.

Similarly, in a federal antitrust case involving allegations that the defendant paid generic manufacturers to delay marketing of generic equivalents to the defendant's immunosuppressant drug, a federal court held that Dr. Kessler could not testify as to numerous legal conclusions, including that the defendant's submission to the FDA "violated the law, constituted fraud on the FDA, or was otherwise improper" and that the defendant's requested "labeling change . . . would violate the law." *In re Prograf*, 2014 WL 7641156, at *1-2. As the court explained, Dr. Kessler could not testify regarding his "interpretation of the relevant laws and regulations or the law of fraud more generally" because he did not possess the necessary expertise and because such testimony would be unfairly prejudicial under Federal Rule of Evidence 403. *Id.* at *2. The court also went on to explain that such testimony would not constitute proper expert testimony, regardless of Dr. Kessler's qualifications: "Dr. Kessler is not—and, indeed, cannot be—a legal expert. It is for the court alone to instruct the jury on what the law is." *Id.*[84]

[84] Numerous other courts have similarly excluded expert opinions that contain legal conclusions on the ground that they constitute impermissible expert testimony. *See, e.g.*, *Flickinger*, 492 F. App'x at 224 (district court properly excluded opinions in premises liability action regarding "dangerous condition" and "negligence," which are "legal terms of art that courts commonly hold cannot be

Even assuming Drs. Kessler and Plunkett's regulatory opinions had any pertinence to the fundamental question of causation, their testimony would still flout these rudimentary standards, providing independent grounds for exclusion. This is so because Dr. Kessler seeks to opine on a number of legal topics, including the "regulatory standards for cosmetics" and whether the J&J defendants complied with those standards.[85] For example, according to Dr. Kessler, the J&J defendants violated regulatory and industry standards by failing to "substantiate the safety of their talcum powder products."[86] Relying on various FDA regulations, Dr. Kessler asserts that "if there is a reasonable basis for an association between talcum powder products and ovarian cancer, a warning about increased risks of ovarian cancer needed to be made."[87] And Dr. Kessler likewise claims that "if asbestos or

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the subject of expert testimony"); *Holman*, 563 F. Supp. 2d at 472 ("Saulino's report is replete with legal conclusions and speculations that ultimately render his entire report deficient."); *FedEx Ground Package Sys., Inc. v. Applications Int'l Corp.*, 695 F. Supp. 2d 216, 221-23 (W.D. Pa. 2010) (excluding expert's legal opinions; "[a] significant portion of Dr. Shamos' report references case law and federal statutes, and an entire section of the report sets forth exactly what its heading indicates, 'Legal Principles'").

85 (Kessler Rep. ¶¶ 13-19; *id.* ¶¶ 40, 64-74.)

86 (*Id.* ¶¶ 64-65.)

87 (*Id.* ¶ 70.) Dr. Kessler's so-called expert opinion on these points should be excluded for the additional reason that it consists of little more than a verbatim regurgitation of selective quotations from the IARC asbestos monograph. This is not a proper expert opinion because Dr. Kessler does not have the expertise necessary to independently evaluate IARC's conclusions. "A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in

asbestiform fibers (fibrous talc) were found in talcum powder products, talcum powder products would be adulterated under the Federal Food Drug and Cosmetics Act."[88]

Dr. Plunkett likewise delves into specific FDA regulations (e.g., 21 C.F.R. § 740.1), juxtaposing the requirements applicable to cosmetic manufacturers with those that govern drug manufacturers.[89] Dr. Plunkett states that "unlike drugs, cosmetics are expected to carry warnings based on a standard of a ***possibility*** of health hazard, not on having evidence of a ***causal*** association between a health effect and the cosmetic product or ingredient."[90] And according to Dr. Plunkett, the J&J defendants' talcum powder products should have contained an ovarian cancer warning given the risk that "ovarian cancer *may* be associated with the use of" such products.[91]

In short, "[i]t is for the court alone to instruct the jury on what the law is." *In re Prograf*, 2014 WL 7641156, at *2. Accordingly, Drs. Kessler and Plunkett's

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a different specialty." *Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002).

88 (Kessler Rep. ¶ 72.)

89 (*See* Plunkett Rep. ¶ 22.)

90 (*Id.* (emphases added).)

91 (*Id.* ¶¶ 105-06.)

legal opinions should be excluded under *Daubert*.[92]

B. Drs. Kessler And Plunkett's Factual Narratives Are Also Not Proper Expert Testimony.

Drs. Kessler and Plunkett's opinions also do not constitute proper expert testimony to the extent they are based on a review of documents that jurors are equally capable of assessing. *See, e.g.*, *Bracco*, 627 F. Supp. 2d at 441-42 (explaining that experts may not "simply summarize the facts and the depositions of others"; "to the extent that [expert's] testimony reflected no more than his summary of, and spin on, internal GEH documents, the Court finds that such testimony is unhelpful to the Court as the trier of fact and excludes such testimony from the record") (quoting *Crowley v. Chait*, 322 F. Supp. 2d 530, 553 (D.N.J. 2004)); *Jeasonne v. Sutherland Bldg. Material Ctrs., L.P.*, No. 12-1905, 2013 U.S. Dist. LEXIS 130046, at *6-7 (W.D. La. Sept. 11, 2013) ("the court finds that defendants' *Daubert* motion should be granted as to Howard's proposed expert report" because the opinions "simply summarize the evidence which will be presented to the jury"); *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008) ("simply summariz[ing] a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not

[92] Dr. Plunkett's regulatory opinions are all the more impermissible since they far outstrip her expertise. As the *Echeverria* court recognized, "although she may have taken courses on FDA matters and give[s] advice on same, she is not qualified to opine as to FDA regulations or their applicability to labeling." Plunkett *Echeverria* Ruling at 6.

amount to expert testimony"), *aff'd in part, rev'd in part*, 586 F.3d 547 (8th Cir. 2009). Such testimony must be excluded because it "comes 'dangerously close to usurping the [factfinder's] function' and 'implicates Rule 403 as a needless presentation of cumulative evidence and a waste of time.'" *Bracco*, 627 F. Supp. 2d at 441 (quoting *Crowley*, 322 F. Supp. 2d at 553). This is so because plaintiffs' factual case should be "presented through introduction of documents or non-expert testimony," and not expert testimony that simply "regurgitat[es] factual information" with the false imprimatur of some special knowledge on the subject. *Pritchett v. I-Flow Corp.*, No. 09-cv-02433-WJM-KLM, 2012 WL 1059948, at *7 (D. Colo. Mar. 28, 2012); *see also, e.g.*, *XpertUniverse, Inc. v. Cisco Sys., Inc.*, No. 09-157-RGA, 2013 WL 865974, at *3 (D. Del. Mar. 7, 2013) ("To the extent his opinions constitute the unfiltered regurgitation of what other people told him . . . the 'expert' testimony adds nothing and therefore is not helpful to a jury."); *Dep't of Toxic Substances Control v. Technichem, Inc.*, No. 12-cv-05845-VC, 2016 U.S. Dist. LEXIS 33379, at *2 (N.D. Cal. Mar. 15, 2016) (expert evidence was inadmissible under Rule 702 because "[w]hen he is not simply speculating, Dr. Everett often does no more than regurgitate information given to him by other sources").

Dr. Kessler's report largely "regurgitat[es] factual information" and packages it as expert opinion. For example, in a section titled "Defendants'

statements that cosmetic manufacturers have responsibility to substantiate the safety of their product," Dr. Kessler simply quotes at length from various internal company documents and prior testimony that any lay juror could easily understand for him or herself:

- "In a June 24, 2003 PowerPoint Johnson & Johnson stated that Johnson's Baby products are 'assessed for safety based on the intended use.'"[93]

- "The same PowerPoint continued, 'Our baby products are composed of a variety of ingredients obtained from reputable trusted suppliers. We hold these suppliers to high standards of material safety, purity and quality based on our best for baby standards.'"[94]

- "In a June 1, 2010, PowerPoint presentation . . . then Senior Product Director,"[95] wrote that "[a]ll final baby product formulations are comprehensively assessed for safety . . . Johnson's Brand is responsible for the ethical management of health, safety, and environmental aspects of our products through their total lifecycle."[96]

- "On October 15, 2012, Lorena Telofski testified on behalf of Johnson & Johnson that Johnson & Johnson goes 'through a process to substantiate safety for the present use. If it doesn't meet the threshold of safety for present use, it is not going to go on the market.'"[97]

Nowhere in these verbatim quotations of straightforward statements does Dr. Kessler engage in any expert analysis. Instead, he simply "regurgitat[es] factual

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93 (Kessler Rep. ¶ 44 (quoting JNJTALC000777136).)

94 (*Id.* ¶ 46 (quoting JNJ000367483).)

95 (*Id.* ¶ 47.)

96 (*Id.* ¶ 47 (alteration in original) (quoting JNJ000438939-41).)

97 (*Id.* ¶ 49 (citation omitted).)

information" that falls well outside the proper scope of expert testimony and should therefore be excluded. *Pritchett*, 2012 WL 1059948, at *7; *see also In re Prempro*, 554 F. Supp. 2d at 887.

Dr. Plunkett similarly devotes a significant portion of her report to offering her advocacy-based interpretation of record evidence. In particular, she attempts to describe what various "[d]ocuments show" about the actions of defendants taken at various points in time and defendants' motivations for taking those actions.[98]

For example, in attempting to describe the J&J defendants' supposed "efforts to influence the science around the issue of asbestos in talc and the link of talc with ovarian cancer,"[99] Dr. Plunkett simply quotes from a decades-old statement made by a Johnson & Johnson employee to the then-FDA Commissioner stating, "Our very preliminary calculation indicates that substantial asbestos can be

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98 (Plunkett Rep. ¶ 78 ("[I]n the 1970s, documents show that Johnson & Johnson made efforts to influence the science around the issue of asbestos in talc and the link of talc with ovarian cancer.") (citing P-0055; P-0344; P-0002); *id.* ¶ 83 ("Publicly available documents show that PCPC has been intimately involved with talc safety issues over the period from the early 1970s up to today") (citation omitted); *id.* ¶ 93 (testifying about supposed "influence" defendants exerted on the National Toxicology Program based on her "review of the depositions and documents"); *id.* ¶ 95 ("Deposition testimony and documents show that, in the context of my opinions that industry undertook significant efforts to influence regulatory bodies and the science concerning the safety assessment of talcum powder products, the Center for Regulatory Effectiveness (CRE) played an important role.").)

99 (*Id.* ¶ 78.)

allowed safely in a baby powder."[100] Dr. Plunkett goes on to quote additional statements from the same document, including the assertion that "if the results of any scientific studies show any questions of safety [regarding] talc, Johnson & Johnson will not hesitate to take it off the market."[101] But Dr. Plunkett provides no expert analysis with respect to the purported "influence" that the multiple quotations supposedly evince, confining her "opinions" to her subjective interpretation of the record evidence. She is simply trying to use her status as an "expert" to lend more credence to plaintiffs' counsel's theories and arguments.

For these reasons, too, Drs. Kessler and Plunkett's opinions should be excluded under Rule 702.

C. Dr. Plunkett's Opinions Regarding Defendants' State Of Mind Do Not Constitute Admissible Expert Evidence.

Dr. Plunkett's opinions are separately inadmissible to the extent they seek to divine defendants' state of mind – i.e., their supposed knowledge of the alleged ovarian cancer risk and their purported goals and motivations.

This Court has recognized that "experts cannot opine on intent." *Bracco*, 627 F. Supp. 2d at 440 (striking expert who "purported to divine what [the defendant] was 'trying' to do with its marketing strategy and what it believed was right or wrong"). Judge Simandle has similarly held that "experts may not provide

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100 (*Id.* (quoting P-0660).)

101 (*Id.* (emphasis omitted) (quoting P-0660).)

testimony concerning 'the state of mind' or 'culpability' of [d]efendants" because "the question of intent constitutes a 'classic jury question and not one for experts.'" *Krys v. Aaron*, 112 F. Supp. 3d 181, 203 (D.N.J. 2015) (citations omitted). Consistent with these principles, courts regularly preclude experts from offering opinions as to intent or motive. *See, e.g.*, *id.* at 205 ("Defendants' motion will be granted to the extent it seeks to exclude Mr. Vinella's testimony concerning [d]efendants' state of mind (by, for example, testifying that [d]efendants acted 'willfully' or 'knowingly') . . . ."); *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prods. Liab. Litig.*, 181 F. Supp. 3d 278, 294 (E.D. Pa. 2016) (excluding expert testimony about the defendants' "corporate state of mind" because it could invade the province of the jury and/or offer inappropriate legal conclusions); *Bartoli v. Novartis Pharm. Corp.*, No. 3:13-0724, 2014 WL 1515870, at *5 (M.D. Pa. Apr. 17, 2014) (holding that plaintiff's expert "may not opine on whether [defendant] acted in good faith or otherwise opine as to [defendant]'s intent or motivations"); *Wolfe v. McNeil-PPC, Inc.*, 881 F. Supp. 2d 650, 661-62 (E.D. Pa. 2012) (excluding "expert testimony regarding the state of mind of defendants and the FDA"; "[i]ntent is not a proper subject for expert testimony") (citation omitted).

The *Echeverria* ruling is once again instructive. There, Dr. Plunkett sought to testify that "defendants downplayed the risks of talc and actively determined not

to tell consumers of them."[102] As the court recognized, "[t]his testimony [was] based solely on reading documents . . . and then opining as to the mental state of individuals in the corporation." *Id.* "This is not permissible," the court explained, because "expert testimony is not needed on this subject."[103] Rather, "[t]he jury c[ould] be instructed as to the applicable law," and "plaintiff c[ould] put in evidence those documents and testimony that show corporate activity and may argue from that."[104]

The same is true here. Just as she tried to do in *Echeverria*, Dr. Plunkett seeks to divine defendants' state of mind by opining on what the J&J defendants knew about the purported risks posed by talc and when they knew it.[105] She also speculates about defendants' intentions and motivations. For example, Dr. Plunkett claims that "[d]ocuments from" the 1970s "show that the ***goal*** was to

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102 Plunkett *Echeverria* Ruling at 6.

103 *Id.* at 6-7.

104 *Id.* at 7. *See also Strum*, 2013 WL 3242715, at *1 (excluding Plunkett's testimony "relating to [d]efendant's state of mind, motives and intent").

105 (*See, e.g.*, Plunkett Rep. ¶ 77 ("Johnson & Johnson knew or should have known that use of cosmetic talc body powders had been reported to lead to lung injury when talc was inhaled . . ."); *id.* ¶ 106 ("A review of internal company documents . . . shows that talc ingredient manufacturers and the manufacturers of talcum powder products were following the published literature and were also intimately involved in the safety assessments of talc over the years. . . . Thus, the defendants were at least aware for decades that ovarian cancer *may* be associated with the use of talcum powder products."); *id.* ¶ 112 (providing a bulleted summary of internal company documents that "support [Plunkett's] opinions that defendants were aware that talcum powder products may be associated with a health hazard").)

mount a defense strategy around talc and to ensure that the products continued to be sold without regulation."[106] And once again, based solely on her "review of the depositions and documents," Dr. Plunkett seeks to opine that "there is evidence that industry had no interest in sponsoring any new research or did not want to spend the money on such research."[107]

"[R]eading documents . . . and then opining as to the mental state of individuals in the corporation," is "not permissible" expert testimony.[108] For this reason, too, Dr. Plunkett's opinions should be excluded under Rule 702 and *Daubert*.

CONCLUSION

For the foregoing reasons, the J&J defendants respectfully request that the Court exclude Drs. Campion, Zambelli-Weiner and Kessler's opinions in full, and all of Dr. Plunkett's non-causation-related opinions.

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106 (*Id.* ¶ 93 (emphasis added) (citing P-57; P-86; P-87; P-88; P-90; P-20).)

107 (*Id.*)

108 Plunkett *Echeverria* Ruling at 6-7.

Dated: May 7, 2019

Respectfully submitted,

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